REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 29, 30 and 32-48) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides hygienic protection for endoscopes, so that such instruments, which have become highly valuable medical diagnostic and procedure tools, can be readily re-used on a patient following recent use on a prior patient. Endoscopes, lacking proper protection against contamination, must generally be dismantled after each use and thoroughly cleaned, which is both time-consuming and quite expensive.

The present invention, as now claimed, provides hygienic protection for an endoscope, which includes a cover, which is closed at its distal end and which is transparent for optical information, at least on the front side thereof, with the cover able to be rolled thereon in a direction of the axis of the endoscope, and including a material that is air-tight, watertight and impermeable to pathological microorganisms with connection of the cover to the working channel to the distal end of the cover being made airtight, watertight and impermeable to pathological microorganisms. One or more working channels for the endoscope extend in a parallel position in relation to the endoscope and terminate in an open manner on the distal end of the cover – the working channel being connected only to the distal end of the cover. The working channels are positioned between the outside of the endoscope and the inner side of the cover. There is only a single vacuum channel,

having one or more openings, which terminates at the inside of the cover in a direction facing the endoscope, which is a "dedicated" vacuum and is in addition to the separate working channels. The vacuum channel is used for pressing the cover onto the endoscope upon the application of sub-atmospheric pressure, or suction, through the vacuum channel. As explicitly claimed, the working channel(s) and the single vacuum channel are entirely separate from one another, in that the one or more working channels are not useful for use as a vacuum channel, and vice versa, in contrast to the applied prior art.

More particularly, the single vacuum channel of the presently claimed invention terminates in an open manner within the envelope of the endoscope protection and can have additional side openings. These side openings advantageously terminate at the inside of the cover on the side of the cover (*i.e.*, an inner side or inner surface of the cover) facing in a direction of the endoscope. When a vacuum is applied to this channel, the air located between the cover and endoscope shaft is sucked out with the consequence being that the cover is drawn firmly, or pressed, onto the endoscope. The vacuum is then maintained during the examination. Thus, a fixed connection between the cover and endoscope is produced advantageously and rapidly after the endoscope has been introduced into the cover, which is dimensioned somewhat larger in the interior diameter, preferably in the proximal part.

During application of the hygiene protection, one hand of the medical practitioner fixes the freely movable working channels and the vacuum channel on the endoscope shaft, while the practitioner's other hand rolls on the cover above the channels. The

combination of a protective cover, with its own working channels, extends outside of the endoscope with the protective cover and the working channels being connected to one another in the distal region of the cover in an airtight and germ-free manner. For attachment of the protection cover in accordance with the presently-claimed invention, the distal end of the cover is pushed onto the endoscope, so that the front face, which is transmissible for optical information, is correctly positioned, *i.e.*, positioned parallel to the distal end of the endoscope. The optical contact between the endoscope and the transparent front face of the cover is preferably produced by means of a fluid, such as microscope immersion oil, which ideally has the same refractive index as the lens of the endoscope.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and single, dedicated vacuum channel for enhanced hygiene, in which the openings of the vacuum channel terminates at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope and is used for drawing, or pressing, the cover onto the endoscope, either disclosed or suggested.

By the present amendments, Applicant has amended independent Claim 29 (and Claims 30 and 32-46 via dependency) to incorporate the subject matter of dependent Claim 31, which specifies that the cover of the claimed apparatus includes "a material that is airtight, watertight and impermeable to pathological microorganisms with

connection of said cover to said working channel to said distal end of said cover being made airtight, watertight and impermeable to pathological microorganisms." Independent Claim 29 has further been amended to specify that the single vacuum channel acts --for pressing said cover onto said endoscope via application of sub-atmospheric pressure--, in contrast to the applied prior art of Silverstein, as will be further explained.

Independent method Claims 47 and 48 have each been amended to specify that the step of applying sub-atmospheric pressure to the single vacuum channel is performed --for pressing said cover onto said endoscope--.

Turning now, in detail, to an analysis of the Examiner's prior art rejections, in the most recent Office Action, being the fifth Office Action, the Examiner has rejected Claims 29-38, 42, 47 and 48 as being anticipated, pursuant to 35 U.S.C. §102(b), by Silverstein *et al.*, U.S. Patent No. 4,646,722, on the overall contention that Silverstein *et al.* discloses an endoscope (and related method) for hygiene protection, that includes a cover that is closed at a distal end and transmissible for optical information, a working channel extending parallel and being connected only to the distal end of the cover and positioned between an outer side of the endoscope via an inside of the cover, and a vacuum channel having at least one opening and terminating at the inside of the cover. The Examiner has also contended that Silverstein *et al.* teaches that the vacuum channel "is a different channel 64 from said working channel," thereby anticipating that claimed by the instant Applicant in the enumerated claims of the anticipation rejection.

Separately, the Examiner has rejected Claims 29 and 43-45 as being obvious,

pursuant to 35 U.S.C. §103(a), over Silverstein, taken in view of Kuramoto, U.S. Patent No. 5,630,795. As part of the obviousness rejection, the Examiner has acknowledged (at 6, ¶ 11) that:

> "Silverstein fails to positively disclose a single vacuum channel, having at least one opening, and terminating at said inside of said cover with said at least one opening terminating inside of said cover in a direction facing said endoscope, said single vacuum channel being a single dedicated channel that is a different channel from said working channel."

In light of the foregoing acknowledgment by the Examiner regarding the scope of the Silverstein *et al.* disclosure, the Silverstein *et al.* reference should no longer be reasonably or fairly viewed as an anticipatory reference against Applicant's claims. (*See*, Silverstein *et al.* at Col. 7, lines 26-28 ("[T]he biopsy channel **36** can be used, as illustrated in FIG. 4, for suction by connecting the channel **36** to a conventional suction device through a valve **54**."), Silverstein *et al.* thereby teaching the use of a biopsy channel as also being useful for a suction, or vacuum, channel, and consequently failing to teach or suggest the use of a single vacuum channel that is "dedicated" as being solely the vacuum channel, as now recited in Applicant's independent Claim 29.)

Consequently, Applicant respectfully contends that the Examiner's 35 U.S.C. §102(b) anticipation rejection of Claims 29-38, 42, 47 and 48, as issued in the fifth Office Action, has been overcome and should now be appropriately withdrawn.

With respect to the Examiner's separate 35 U.S.C. §103(a) rejection of Claims 29 and 43-45 as being obvious over Silverstein *et al.*, taken in view of Kuramoto, independent Claim 29, as now amended, incorporates the subject matter of prior dependent Claim

31, which has not been rejected as part of the foregoing obviousness rejection.

Accordingly, withdrawal of the Examiner's 35 U.S.C. §103(a) obviousness rejection applying Silverstein *et al.*, taken in view of Kuramoto, is respectfully submitted to be proper.

Further, as part of the fifth Office Action, the Examiner has rejected Claims 29, 41 and 46 as being anticipated, pursuant to 35 U.S.C. §102(b), by Sidall, U.S. Patent No. 4,741,326. Similarly, in light of Applicant's incorporation of the subject matter of dependent Claim 31 into independent Claim 29, Applicant respectfully contends that the anticipation rejection applying Sidall has been overcome (or has otherwise been rendered moot) and should now be appropriately withdrawn.

Applicant therefore respectfully submits that apparatus Claims 29, 30 and 32-46 are now allowable over the prior art applied in the fifth Office Action.

Independent method Claims 47 and 48, as previously mentioned, have been rejected in the latest Office Action by the Examiner as being anticipated, pursuant to 35 U.S.C. §102(b), by Silverstein *et al.* on the contention that the applied citation effectively teaches a method comprising the steps of coating an inner side of a window at a distal end of the cover for producing optical contact between the window and the optical channel of the endoscope; introducing a distal end of the endoscope into the cover with the cover being open at a proximal end and closed at a distal end thereof; rolling the cover onto, or unfolding the cover with, an enclosure of the endoscope and the working

channel; and applying a sub-atmospheric pressure (or suction; Col. 7, lines 60-65) to a single vacuum channel (64) for fixing the working channel (36, 38) at the distal end (32) of the cover, thereby anticipating Applicant's method claims, as the Examiner has contended.

In addition to the foregoing rationale for why the subject matter of method Claims 47 and 48 is patentable over Silverstein *et al.*, Applicant further wishes to add that the last step recited by Applicant in the claimed method is that of "applying sub-atmospheric pressure to said single vacuum channel for pressing said cover onto said endoscope." Silverstein *et al.* teaches (at Col. 7, line 60 – Col. 8, line 2) that "pressurized gas" emanating from an "inflation nozzle" (64) is used for collapsing the sheath "to a tight fit on the endoscope." Upon completion of the endoscopy, the "pressurized gas is once again applied to the inflation nozzle **64**, thereby expanding the elastomeric material **48** and allowing it to be easily slipped off the endoscopic core **12**." The "pressurized gas" used by Silverstein *et al.* for fitting the cover onto the endoscope is not of "sub-atmospheric pressure," but of a pressure that is greater than atmospheric pressure, since the pressurized gas is applied from an "inflation" nozzle and used for expanding the elastomeric material to place the sheath onto the endoscope and for later removing the sheath once the endoscopy is completed, in sharp contrast to that recited in Applicant's method Claims 47 and 48.

The vacuum channel in Silverstein *et al.* is a biopsy channel (36), unlike the vacuum channel of the claimed invention, and in Silverstein *et al.*, the vacuum/biopsy

channel is used for extracting a small objects and liquids from a patient (Col. 7, lines 25-31.)

In light of the foregoing, it is respectfully contended that independent method Claims 47 and 48, as now amended, are neither anticipated by, nor obvious over, Silverstein *et al.*, and that withdrawal of the Examiner's 35 U.S.C. §102(b) anticipation rejection of the fifth Office Action is respectfully requested.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 29, 30 and 32-48) recite a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and single, dedicated vacuum channel for enhanced hygiene, in which the openings of the vacuum channel terminates at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope, which is patentably distinguishable over the prior art. According-

ly, withdrawal of the outstanding rejection and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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